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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,731	09/29/2003	Takahiro Imada	K-1970DIV	6740
32628	7590	05/24/2007	EXAMINER	
KANESAKA BERNER AND PARTNERS LLP 1700 DIAGONAL RD SUITE 310 ALEXANDRIA, VA 22314-2848			MARX, IRENE	
		ART UNIT	PAPER NUMBER	
		1651		
		MAIL DATE	DELIVERY MODE	
		05/24/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/671,731	IMADA ET AL.
	Examiner	Art Unit
	Irene Marx	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 April 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4-7 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 4-7 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

Art Unit: 1651

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/245/07 has been entered.

Claims 4-7 are being considered on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-7 are rejected under 35 U.S.C. 101 because the claims read on plants that are found in nature and thus, are unpatentable to applicant.

While claim 4, recites "artificially introduced" as a product by process limitation, the plant as claimed cannot be readily distinguished from the naturally occurring plant, since the microorganisms were obtained from a grass. Thus they are naturally found as symbionts on grasses.

Mere "introduction", whether natural or artificial, does not indicate that the fungus is permanently inserted in the plant, for example, or whether it will be washed off by the next rain or irrigation. That the fungus can be a symbiont of certain grasses and was isolated therefrom does not imply that just by "artificial introduction" by any means and in any amount the fungal strain will become permanently installed in any *Agrostis*, *Festuca*, *Poa* or *Lolium*, such that the grass is in fact permanently altered.

As to claim 5, there is no clear indication that a seed obtained from an adult grass that has been infected does in fact contain the symbiotic fungus

Regarding claims 6-7, there is no assurance that the plant grown from an infected seed, will in fact be infected. But even if it does, the plant cannot be readily distinguished from the naturally occurring plant, as claimed.

Art Unit: 1651

There is no claim designated limitation to clearly delineate a change in the grass that would distinguish the plant from a naturally occurring grass. The mode and effect of “artificial introduction” does not affect the plant *per se*.

Consequently, the claims do not embody patentable subject matter as defined in 35 USC 101. See, e.g., American Wood v. Fiber Disintegrating Co., 90 U.S. 566 (1974); American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931); Funk Brothers Seed. Co. v. Kalo Innoculant Co., 33 U.S. 127 (1948); Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980).

Claims 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is confusing in that the step of “is artificially introduced” does not specify with any particularity the site or mode of “introduction” or the amount to be “introduced” artificially.

Claim 4 is vague, indefinite and confusing in the recitation of “said symbiotic fungus producing chanoclavine as a final metabolic product”. The nature of “a final metabolic product” is uncertain, since this implies that there are many “final metabolic products”.

Claim 6 is confusing since the cannot be determined whether the grass obtained from the infected seed is or is not infected with the symbiotic fungus

Claim 7 is vague and indefinite in that there is no clear claim limitation as to whether the hybrid grass intended is or is not infected by the symbiotic fungus or to what extent.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The arguments directed to the sole production of chanoclavine as the final product is confusing, since the claims are directed to the production of “chanoclavine as a final product”. It is recommended that “the final product” be indicated to conform with the language of the issued claims directed to a fungus “which produces one chanoclavine as the final metabolic product.”

Art Unit: 1651

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Porter *et al.*

The claims are broadly drawn to any *Agrostis*, *Festuca*, *Poa* or *Lolium*, which has been inoculated with certain strains of *Neotyphodium*.

Porter discloses a plant which is infected with an endophyte that produces chanoclavine.

It is deemed that the process of infection or the process by which the plant is obtained does not affect the product. (See, e.g., page 874). It is noted that ryegrass belongs to the genus *Lolium*.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially

Art Unit: 1651

identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Claims 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Cagas *et al.*.

The claims are broadly drawn to any *Agrostis*, *Festuca*, *Poa* or *Lolium*, which has been inoculated with certain strains of *Neotyphodium*.

Cagas *et al.* discloses a plant which is infected with an endophyte that produces chanoclavine, such as *Neotyphodium*. It is deemed that the process of infection or the process by which the plant is obtained does not affect the product. (See, e.g., page 366). It is noted that plants such as *Lolium* and *Festuca* are infected.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-

Art Unit: 1651

process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the claims are not "product by process". Yet the claim 4 as written is to:

4. (Currently amended) A plant according to claim I, wherein said plant is a grass selected from the group consisting of *Agrostis*, *Festuca*, *Poa* and *Lolium*
into which a symbiotic fungus is artificially introduced,
wherein said symbiotic fungus is a filamentous fungus belonging to the genus *Neotyphodium*, and said symbiotic fungus is one selected from the group consisting of FERM BP-08480, FERM BP-08481 and FERM BP-08482, deposited at the Japanese National Institute of Bioscience and Human Technology, said symbiotic fungus producing chanoclavine as a final metabolic product.

The claims are directed to plants any *Agrostis*, *Festuca*, *Poa* or *Lolium* having certain *Neotyphodium* strains "artificially introduced". The product by process aspect of the invention is the process step "**into which a symbiotic fungus is artificially introduced**".

There is nothing in the claim to indicate that the plants are altered in any way by the "introduction". Mere "introduction", whether natural or artificial, does not indicate that the fungus is permanently inserted in the plant, for example, or whether it will be washed off by the next rain or irrigation. That the fungus can be a symbiont of certain grasses and was isolated therefrom does not imply that just by "artificial introduction" by any means and in any amount

Art Unit: 1651

the fungal strain will become permanently installed in any *Agrostis*, *Festuca*, *Poa* or *Lolium*, such that the grass, is, in fact, permanently altered or that it can be distinguished from other grasses of the same species harboring a fungus that produces chanoclavine as a final metabolic product.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Irene Marx
Primary Examiner
Art Unit 1651